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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,499	06/05/2001	James E. Kipp	1417Y P 478	6158

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/874,499

Applicant(s)

KIPP ET AL.

Examiner

Simon J. Oh

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Election/Restrictions*

The election requirement of 25 September 2002 has been withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stainmesse *et al.* (U.S. Patent No. 5,133,908)

The Stainmesse *et al.* patent teaches methods of producing nanoparticles comprising first, preparing a liquid phase consisting essentially of a solution of the substance in a solvent or in a mixture of solvents to which may be added one or more surfactants; second, preparing a second liquid phase consisting essentially of a non-solvent or a mixture of non-solvents for the substance and to which may be added one or more surfactants, the non-solvent or the mixture of non-solvents for the substance being miscible in all proportions with the solvent or the mixture of solvents for the substance; third, adding one of the liquid phases prepared in first or second step to the other with moderate stirring so as to produce a colloidal suspension of nanoparticles of the substance; and fourth, if desired, the removal of all or part of the solvent or the mixture of solvents for the substance and of the non-solvent or the mixture of non-solvents for the substance

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so as to produce a colloidal suspension of nanoparticles of the desired concentration or to produce a powder of nanoparticles (See Abstract; Column 2, Lines 32-52; and Claim 1). Various organic compounds may serve as the substance in the disclosed process, including polymers, waxes, biologically active substances, or pigments (See Column 2, Line 60 to Column 3, Line 38). Solvents may be selected among various organic solvents, including methanol, ethanol, isopropanol, and acetone (See Column 3, Lines 46-68). Ethanol and distilled water are mentioned as examples of non-solvents (See Column 4, Lines 1-14). Surfactants suitable for use in the disclosed process includes anionic surfactants, such as sodium lauryl sulfate; cationic surfactants, such as quaternary ammonium; and non-ionic surfactants, such as ethers formed between fatty alcohols, and polyoxyethylene glycols (See Column 4, Lines 15-23). The disclosed process can produce nanoparticles smaller 500 nm, and in particular 200 nm in size.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.*

The relevant portions of Stainmesse *et al.* are detailed in the above rejection of Claims 1, 5-7, and 11 under 35 U.S.C. 102(b).

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It is the position of the examiner that Claims 1-17 cannot be considered patentable over the disclosure of Stainmesse *et al.*

Claims 2-4 are directed to the use of phospholipids in the instantly claimed process. However, it is the position of the examiner that the limitations of these claims would be known to one of ordinary skill in the art, in light of what examiner believes to be a reasonably broad interpretation of the disclosure of Stainmesse *et al.*

Claims 8-10 are directed to the selection of particular solvents and surfactants for use in the applicant's claimed invention. It is the position of the examiner that the applicant has not established a patentably critical distinction of the choice of these particular components over the disclosure of the prior art.

Claim 12 is directed to methods steps of solvent and surfactant removal, which the examiner believes to be well known in the art, and is therefore not critical to the instantly claimed invention.

Claims 13-17 seem to be directed to methods of preparing a stabilized suspension or a pharmaceutical composition, which the examiner sees as not being to the claimed methods of preparing sub-micron-sized particles of an organic compound. The applicant has also disclosed such steps as being optional.

The instantly claimed invention is *prima facie* obvious.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
February 19, 2003

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
Au 1615